Argument

In the record and in this brief, the Appellant traverses all adverse statements and all grounds of rejection concerning the present application. The Appellant contends the following in support of the patentability of the claims on appeal:

1. Claims 21, 22, 25, 26, 28, 29, 40 and 41 are patentable over McLaughlin.

McLaughlin discloses a multipolar joint endoprosthesis. In general, it consists of multiple wedge-shaped, cylindrical components rotating perpendicular to their planes of effacement, plus proximal and distal components. The proximal component is:

> "contoured to fit the the proximal side of a surgically prepared joint (i.e., the glenoid fossa of the gleno-humeral joint, the acetabulum of the hip, etc.)"

and the distal component is:

> "contoured to fit the distal side of the surgically prepared joint or into the surgically prepared intramedullary canal distal to the involved joint (i.e., intramedullary canal of the humerous, hip, etc.)."

See, column 1, lines 19-32. Problems in the art are noted at column 1, lines 5-10: dislocation, component dissociation, bony wear, acetabular protrusio, pain, polyethylene wear, limited range of motion, etc. At column 1, lines 48-56, it is stated:

> "Since there is no motion at the bone-prosthesis interfaces, it is hypothesized that many of the problems of previously proposed endoprostheses would be resolved (i.e., bony wear, acetabular protrusio, pain, etc.). In addition, the components are inseparable except by surgical manipulation, as noted above, avoiding the problems of dislocation, dissociation of components, etc. Finally, by allowing motion at multiple component interfaces, the problems of polyethylene/component wear and limited range of motion are eliminated."

Within the paragraph bridging columns 1 and 2, from column 1, line 66, to column 2, line 2, McLaughlin states:

> "[T]he present invention is represented as a hip endoprosthesis. However, it is not meant to imply that the present invention is limited to use in the hip."

In detail, as at column 2, lines 33-35, McLaughlin states:

> "The proximal component 12 is firmly affixed to the proximal bony landmark (e.g., pelvis) 14 by means of

> methylmethacrylate bone cement, screws 20, bony ingrowth, etc., in such a way that no motion occurs at the proximal component-bone interface 17."

See, FIGS. 1 and 3-5. Also, as set forth at column 2, lines 46-49, a screw tract 23 is provided in the proximal component 12. See, FIGS. 3-5.

Claim 21

McLaughlin has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant.

First, it relates to large ball and socket joints of the shoulder and hip. Manifestly, the problems addressed are those of total hip and shoulder joints. Nothing else is taught, expressly or impliedly, even by the general word, "etc." Thus, the cylindrical components 11 of McLaughlin are large and would not be transferable by size reduction to a small joint. Rather, such an arrangement with its plurality of cylindrical components 11, if it could be envisioned implanted in a small joint, would cause pain and tissue damage such as by stretching of ligaments and tendons. In contrast, claim 21 requires a modular basal thumb joint implant with a head of a size and having an articular surface for mounting and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and a stem of a size for intramedullary insertion in metacarpal bone stock. Compare, Evidence Appendix, p. EA-4, first paragraph, through p. EA-5, second paragraph, which sets forth part of a declaration from Patrick E. Pringle, president of BioPro, Inc., regarding hip and shoulder art not analogous because of size, configuration and implant situs. Giving such evidence weight, akin to that given to that declaration by the Board in Appeal No. 2003-0155 for the finger art of Klawitter et al., U.S. patent No. 5,782,927, helps show how hip or shoulder art would not suggest a modular basal thumb joint implant. See, Related Proceedings Appendix, p. RPA 8, sole full paragraph. The Board in Appeal No. 2007-0570 held too that Smith et al., U.S. patent No. 3,314,420 for a prosthetic implant and methods of making the same, which depicts a femoral component for a hip implant and recites a long list of other implants and products in column 16, does not teach a basal thumb joint implant in the parent. See, Related Proceedings Appendix, p. RPA-20, second full paragraph. Only analogous, pertinent art can be applied. See, e.g., KSR International Co. v. Teleflex Inc., 550 U.S. ___ [82 USPQ2d 1385, 1397] (2007); In re Oetiker, 977 F.2d 1443 [24 USPQ2d 1443, 1445-1446] (Fed. Cir. 1992).

Second, what the Examiner takes for a "head" in McLaughlin is the proximal component 12. That, properly understood, is not a head of a joint or joint prosthesis. The proximal component 12 is fixed with bone screws 20, glue, or bony ingrowth (generally through a rough or porous surface) so that its hemispherical surface does not articulate, in a socket or elsewhere. It has

adjusting screw tract holes 23 and holes for the screws 20 penetrating its hemispherical surface to render it discontinuous. In contrast, claim 21, in addition to that noted above, requires a single, smooth, generally hemispherical, medio-proximally directed articulating surface, with the articulating surface continuous as to its spehericity and uninterrupted up to the end of the articulating surface. Such art is diametrically opposed, and McLaughlin would be inoperable for its intended purposes if his proximal component 12 were to move. Inoperable art cannot be employed to establish a case of obviousness. See, United States v. Adams, 383 U.S. 39 [148 USPQ 479, 483] (1966); In re Gordon, 733 F.2d 900 [221 USPQ 1125, 1127] (Fed. Cir. 1984). Thus, along this line of reasoning the Board in Appeal No. 2003-0155 held that discontinuities in a generally hemispherical surface do not suggest to the ordinary artisan a hemispherical surface that is continuous as to its sphericity. See, Related Proceedings Appendix, p. RPA-8 (finger joint of the Klawitter et al. patent inoperable for its intended purpose if cuts in articulating surface removed, not suggestive of basal thumb joint implant). If McLauglin could be applied, it clearly teaches away from the smooth articulating head of the present claim, which would be strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; In re Hedges, 783 F.2d 1038 [228 USPQ 685, 687] (Fed. Cir. 1986).

Third, the Examiner takes as a "stem" the distal component 13. Taking it thus, it is clear that it does not attach to the "head," i.e., proximal component 12, to project therefrom. The cylindrical components 11 intervene. In contrast, claim 21 requires that the stem be attachable to the head, and when attached it projects from the head. Such emphasizes that the art proposed by the Examiner is widely divergent from and not at all structurally analogous to the art of the present claim. It is so widely divergent it teaches to parts intervening between the head and stem, thus teaching away from the claimed invention. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Furthermore, if the distal component 13 were attached to the proximal component 12, it would be attached perpendicularly. This is not an acute angle of projection found in the claim, and a perpendicular attachment would not suggest an acute one.

Moreover, there nothing eccentric in the attachment of any component to the proximal component 12 of McLaughlin. The site of attachment to the proximal component 12 is directly centered. See, FIGS. 1 and 3-5. In contrast, the eccentric attachment site of the present claim is defined as being "offset from the center of the generally planar end of the head." A standard, central situs of attachment does not suggest an eccentric one.

Finally, it cannot be properly said that it would have been obvious to employ McLaughlin's disclosure for a relevant teaching

in a modular basal thumb joint implant as the ordinary artisan would understand that the body is made of many joints and that when the thumb joint has been injured or diseased it would be desirable to replace it with a prosthesis. That statement of the Examiner is inaccurate and provides nothing to motivate the ordinary artisan to modify McLaughlin into the present claim.

Thus, independent claim 21 distinguishes over McLaughlin.

Claim 22

Claim 22 depends on claim 21. By virtue of its dependence on claim 21, claim 22 distinguishes over McLauglin.

Furthermore, claim 22 requires the general angle of projection that is acute in relation to the generally planar end to the head. As explained above for claim 21, the "stem" of McLaughlin would attach to the "head" perpendicularly to project therefrom. Note, McLaughlin, FIG. 3, features 12, 22 and 26, and 13, 21 and 25. Perpendicular attachment does not suggest acuity; it teaches away, which is strong evidence of unobviousness. Then too, if the "stem," i.e., distal component 13, were to attach to the "head," i.e., proximal component 12, to project from it, it would destroy the operability and intents of McLaughlin. An inoperable reference cannot negative patentability, and the intents of a reference cannot be destroyed to establish a case of obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Gordon, 733 F.2d 900 [221 USPQ 1125, 1127]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claim 25

Claim 25 depends on claim 21. By virtue of its dependence on claim 21, claim 25 distinguishes over McLauglin.

Furthermore, claim 25 requires the eccentric head site for the stem. As explained above for claim 21, McLaughlin's site of attachment to the proximal component 12 is on center. See, FIGS. 1 and 3-5. In contrast, the eccentric attachment site of the present claim is defined through its dependence on claim 21 as being "offset from the center of the generally planar end of the head." A standard, central situs of attachment does not suggest an eccentric one; it teaches away from such a feature, which is strong evidence of unobviousness. Adams, 383 U.S. 39 [148 USPQ at 483-484]; Hedges, 783 F.2d 1038 [228 USPQ at 687]. Moreover, if the "stem," i.e., distal component 13, were to attach to the "head," i.e., proximal component 12 to project therefrom, it would destroy the operability and intent of McLaughlin. An inoperable reference cannot negative patentability, and the intents of a reference cannot be destroyed to establish a case of obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Gordon, 733 F.2d 900 [221 USPQ 1125, 1127].

Claim 26

Claim 26 depends on claim 22. By virtue of its dependence on claim 22, thence 21, claim 26 distinguishes over McLauglin.

Furthermore, the Examiner admits that neither the flanged cross sectional stem profile nor the inwardly curved stem is rendered obvious by McLaughlin. As explained above with respect to claim 25, neither is the eccentric head site for the stem.

Claim 28

Claim 28 depends on claim 21, and further requires that the head has a stem trunion receiving cup in the generally planar end to the head, and the stem has a trunion for being received in that cup. By virtue of its dependence on claim 21, claim 28 distinguishes over McLauglin.

As particularly explained above in the argument for claim 21, McLaughlin's fixed "head," i.e., proximal component 12, is not a head in a sense of having a smooth generally hemispherical articulating surface as required hereby; it teaches away from this invention. And, if the "stem," i.e., distal component 13, were to attach to the "head," i.e., proximal component 12 to project therefrom, it would destroy the intent and operability of McLaughlin. Teaching away is strong evidence of unobviousness; an inoperable reference cannot negative patentability, and the intents of a reference cannot be destroyed to establish a case of obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Gordon, 733 F.2d 900 [221 USPQ 1125, 1127]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claim 29

Claim 29 depends on claim 22, and further requires that the head has a stem trunion receiving cup in the generally planar end to the head, and the stem has a trunion for being received in that cup. By virtue of its dependence on claim 22, thence 21, claim 29 distinguishes over McLauglin.

As particularly explained above with respect to claim 25, the eccentric head site for the stem is not rendered obvious by McLaughlin. And as particularly explained above for claim 28, McLaughlin's fixed "head," is not a head in the sense of having a smooth generally hemispherical articulating surface; it teaches away. And if McLaughlin's "stem" were to attach to his "head" to project therefrom, it would destroy his intents and operability. Teaching away is strong evidence of unobviousness; an inoperable reference does not negative patentability, and the intents of a reference cannot be destroyed to establish a case of obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Gordon, 733 F.2d 900 [221 USPQ 1125, 1127]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claim 40

Jepson claim 40 admits as prior art basal thumb joint implants with a head for mounting and articulating in prepared trapezium and a stem for intramedullary insertion in metacarpal bone. The improvement therewith is head and stem modularity such that the head is removably attachable to the stem.

As set forth within the arguments set forth with respect to claim 21 and applicable here to independent claim 40 as well, McLaughlin has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant.

For one thing, McLaughlin relates to large ball and socket joints of the shoulder and hip. The problems addressed are those of total hip and shoulder joints, nothing else, even by the word, "etc." The cylindrical components 11 of McLaughlin are large and would not be transferable by size reduction to a small joint. Rather, such an arrangement with its plurality of cylindrical components 11, if it could be envisioned implanted in a small joint, would cause pain and tissue damage such as by stretching of ligaments and tendons. In contrast, claim 40 requires a modular basal thumb joint implant with a head of a size and having an articular surface for mounting and articulating with a correspondingly concavely prepared surface of trapezium bone stock, and a stem of a size for intramedullary insertion in metacarpal bone stock. Compare, Evidence Appendix, p. EA-4, first paragraph, through p. EA-5, second paragraph, Mr. Pringle's declaration, regarding hip and shoulder art not analogous because of size, configuration and implant situs. Giving such evidence weight, akin to that given to that declaration by the Board in Appeal No. 2003-0155, helps show how hip or shoulder art would not suggest a modular basal thumb joint implant. See, Related Proceedings Appendix, p. RPA 8, sole full paragraph. The Appeal No. 2007-0570 held that Smith et al., U.S. patent No. 3,314,420, which depicts a femoral implant component for a hip and recites a long list of other implants and products in column 16, does not teach a basal thumb joint implant. See, Related Proceedings Appendix, p. RPA-20, second full paragraph. Only analogous, pertinent art can be applied. See, e.g., KSR, 550 U.S. ___ [82 USPQ2d at 1397]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446].

For another thing, what the Examiner takes for a "head" in McLaughlin, i.e., the proximal component 12, properly understood is not a head of a joint or joint prosthesis. That component 12 is fixed with bone screws 20, glue, or bony ingrowth so that its hemispherical surface does not articulate. That is opposite this claim, and McLaughlin would be inoperable for the stated intended purposes if the component 12 were to move. Inoperable art cannot be employed to establish obviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Gordon, 733 F.2d 900 [221 USPQ at 1127].

Thus, independent claim 40 distinguishes over McLaughlin.

Claim 41

Claim 41 depends on claim 40. By virtue of its dependence on claim 40, claim 41 distinguishes over McLaughlin.

Furthermore, claim 41 requires an acute general angle of projection of the stem with respect to the non-articular surface of the head. The Examiner takes as a "stem" the distal component 13, which clearly does not attach to the "head," i.e., proximal component 12, to project therefrom. The cylindrical components 11 intervene. In contrast, claim 41 requires that the stem project from the head, and this without intervening components such as the cylindrical components 11. The art proposed by the Examiner is widely divergent from and not at all structurally analogous to the art of the present claim. It is so widely divergent it teaches to parts intervening between the head and stem, thus teaching away from the claimed invention. See, Adams, 383 U.S. 39 [148 USPQ at 483-484]; KSR, 550 U.S. ___ [82 USPQ2d at 1399]; Hedges, 783 F.2d 1038 [228 USPQ at 687]. In fact, if the distal component 13 were to be attached to the proximal component 12 in the manner of the present claim, eliminating the cylindrical components 11, it would render McLaughlin inoperable. Inoperable art cannot be applied. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Gordon, 733 F.2d 900 [221 USPQ at 1127].

Also, should McLaughlin's distal component 13 be attached to the proximal component 12, it would be attached perpendicularly. This is not an acute angle of projection required by this claim, and a perpendicular attachment would not suggest an acute one.

2. Claim 23 is patentable over McLaughlin in view of Townley.

Claim 23 depends on claim 21. It further requires the flanged cross-sectional stem profile.

As explained above with respect to claim 21, McLaughlin does not render the base claim obvious. Townley, if both McLaughlin and Townley could be applied, adds nothing that would render base claim 21 obvious, even with respect to its stem limitation "B." As set forth above with respect to base claim 21, McLaughlin has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant. Townley as well, representing a femoral component for a hip implant, is not applicable to a basal thumb joint implant. This, again, has been verified by Mr. Pringle, and confirmed by the Board previously. See, Evidence Appendix, p. EA-4, first paragraph, through p. EA-5, second paragraph; Related Proceedings Appendix, p. RPA 8, sole full paragraph, and p. RPA-20, second full paragraph. Only analogous, pertinent art can be applied. See, e.g., KSR, 550 U.S. ___ [82 USPQ2d at 1397]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446]. See also, In re Sernaker, 702 F.2d 989 [217 USPQ 1, 5] (Fed. Cir. 1983) (references to be related to one another).

Among other things, too, Townley lacks modularity, size of the claimed head and stem, a generally planar end to his head, and so forth. If the features of Townley were to be combined with those of McLaughlin, a person of ordinary skill would be left in the dark as to which features should be present; for example, some possibilities: should there be a fixed distal component? an articulating distal component as head? a generally planar end to a fixed distal component? a generally planar end to an articulating head? a cupped fixed distal component? a cupped articulating head? a simple stem? intervening moving components? a tri-flanged stem? modularity? no modularity? if the size of the implant were made small, should not a tri-flange stem be jettisoned, say, as taught by the Swanson Titanium Basal Thumb Implant (Wright)? should, if made small, modularity be jettisoned as taught by Wright? Thus, at best, the artificial combination has ambiguous teachings, which are not even general guidance. Even general guidance, however, is not enough to establish obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; In re Roemer, 258 F.3d 1303 [59 USPQ2d 1527, 1531] (Fed. Cir. 2001).

3. Claim 24 is patentable under over McLaughlin in view of Lane et al.

Claim 24 depends on claim 21. It further requires the inwardly curved stem.

As explained above with respect to claim 21, McLaughlin does not render the base claim obvious. Lane et al., if it could be applied with McLaughlin, adds nothing that would render base claim 21 obvious, even with respect to its stem limitation "C."

As set forth above with respect to base claim 21, McLaughlin has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant.

Lane et al. represents finger joint art, which is not related to basal thumb joint art. The Examiner admitted in the parent case (05/25/01 Office action, page 2) that finger joint art is independent and patentably distinct from, and unrelated to, basal thumb joint art. He cited different classifications, 623/21.15 vs. 623/21.11, and stated:

> "In the instant case, the different inventions are two types of joints which operate differently and are structurally different. The finger or digit joint is considered an anarthrodial joint, whereas the thumb is a'saddle joint.'"

Moreover, the finger joint of Lane et al. has multiple articulation surfaces and is a total joint implant, and it does

not have head and stem modularity. Thus, in the first instances it does not have a single articulating surface that is continuous as required through the base claim 21. Accordingly, it resembles the implant of Klawitter et al., U.S. patent No. 5,782,927. The Board in Appeal No. 2003-0155 stated about such art:

> "[W]e fail to perceive any teaching, suggestion or incentive which would have led one of ordinary skill in the art to manufacture the Klawitter joint implant without the cuts ... for to do so would render the device unsuitable for its intended purpose. Continuing on the same theme, there is no evidence from which to conclude that one of ordinary skill in the art would have found it obvious to utilize the Klawitter joint implant on the thumb, in view of the different considerations needed for a thumb joint, which are attested to on page 10 of the Pringle declaration."

See, Related Proceedings Appendix, p. RPA-8; Evidence Appendix, p. EA-5, second full paragraph, through p. EA-6. Moreover, the Examiner admitted in the same 05/25/01 Office action, page 2, last paragraph, that modular basal thumb joint art was patentably distinct from the non-modular art. Non-modular finger joint art is even more unrelated. Only analogous art can be applied. See, KSR, 550 U.S. ___ [82 USPQ2d at 1397]; Sernaker, 702 F.2d 989 [217 USPQ at 5]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446].

If the features of Lane et al. were to be combined with those of McLaughlin, a person of ordinary skill would be left in the dark as to which features should be present; for example, some possibilities: should there be a fixed distal component? an articulating distal component as head? a generally hemispherical articulating head? a complex head including shoulders and sphere? a straight stem? a curved stem? intervening moving components? modularity? no modularity? if the size of the implant were made small, should not a curved stem be jettisoned, say, as taught by Wright? should, if made small, modularity be jettisoned as taught by Lane et al., and Wright? At best, the artificial combination has ambiguous teachings, which are not even general guidance. Even general guidance, however, is not enough to establish obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; Roemer, 258 F.3d 1303 [59 USPQ2d at 1531].

4. Claims 31, 32 and 34-36 are patentable over McLaughlin in view of Abouaf et al.

Claims 31 and 32 depend on claims 28 or 29, and further require tapered walls to the cup and trunion to secure the head and stem together. Claims 34, 35 and 36 depend on claims 21, 22 or 28, and further require a ceramic head and a metal stem.

As explained above with respect to claim 21, McLaughlin does not render the base claim obvious since that patent has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant. Abouaf et al., if both McLaughlin and it could be applied, adds nothing that would render base claim 21 obvious.

Abouaf et al., comparable to Townley discussed with respect to claim 23, in one aspect concerns a hip implant, here total, which is not applicable to a basal thumb joint implant. This, again, has been verified by Mr. Pringle, and confirmed by the Board previously. See, Evidence Appendix, p. EA-4, first paragraph, through p. EA-5, second paragraph; Related Proceedings Appendix, p. RPA 8, sole full paragraph, and p. RPA-20, second full paragraph. In another aspect, Abouaf et al. represents a simple, non-modular total knee joint implant. See, FIG. 4. That ginglymous joint implant is not related to a basal thumb joint implant, much less the pertinent art of a modular basal thumb joint implant. Only pertinent art can be applied. See, e.g., KSR, 550 U.S. ___ [82 USPQ2d at 1397]; Sernaker, 702 F.2d 989 [217 USPQ at 5] Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446].

Among other things, too, Abouaf et al. lacks size of the claimed head and stem, a generally hemispherical articulating head, a generally planar end to his head, and so forth. If the features of Abouaf et al. were to be combined with those of McLaughlin, a person of ordinary skill would be left in the dark as to which features should be present; for example: should there be a fixed distal component? an articulating distal component as head? a generally planar end to a fixed distal component? a generally planar end to an articulating head? a generally spherical head? a knee with its condyles? a simple stem? intervening moving components? if the size of the implant were made small, should not modularity be jettisoned, say, as taught by Wright? Thus, at best, the artificial combination has ambiguous teachings, which are not even general guidance. Even general guidance, however, is not enough to establish obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; In re Roemer, 258 F.3d 1303 [59 USPQ2d 1527, 1531] (Fed. Cir. 2001).

Claim 31

The proposed combination fails to suggest tapered walls for securing a head to a stem in a modular basal thumb joint implant as claimed through claims 28 and 21. In particular with the above matter applicable generally, if combined, would the combination lead the ordinary artisan to modularity or not? If so, would the combination lead to the straight, cylindrical walls of McLaughlin, or the tapered walls of Abouaf et al.? Where is

there a suggestion to reduce the size of a hip, shoulder or knee implant? Many features of the combination teach away, which is strong evidence of unobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claim 32

The proposed combination fails to suggest tapered walls for securing a head to a stem in a modular basal thumb joint implant as claimed through claims 29, 22 and 21. In particular with the above matter applicable generally, if combined, would the combination lead the ordinary artisan to modularity or not? If so, would the combination lead to the straight, cylindrical walls of McLaughlin, or the tapered walls of Abouaf et al.? Where is there a suggestion to reduce the size of a hip, shoulder or knee implant? Many features of the combination teach away, which is strong evidence of unobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; Roemer, 258 F.3d 1303 [59 USPQ2d at 1531].

Of note, too, is the acute general angle of projection required with the remaining elements through claim 22. Abouaf et al. teaches a standard perpendicular angle of projection for a hip (FIGS. 1-3) or no stem and head whatsoever (FIG. 4). McLaughlin, as explained with respect to claim 22, further would be inoperable with a stem to head attachment, ignoring that otherwise teaching a perpendicular angle of attachment. This is further evidence of inapplicability of the art and patentability. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Gordon, 733 F.2d 900 [221 USPQ at 1127]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Claims 34, 35 and 36, Taken Separately

A ceramic head with metal stem in a modular basal thumb joint is not suggested by the proposed combination, particularly in light of the subject matter additionally required not only by the base claim 21 on which claim 34 directly depends, but also claim 22 upon which claim 35 directly depends and requires acuity in attachment of the stem to the head, and claim 28 upon which claim 36 depends and requires a stem trunion and a cup in the head for receiving it. In addition to the arguments presented above, which are applicable hereto, note that if combined the combination would be vague about materials in general, and absent impermissible hindsight, gives not even general guidance as to what would be desirable for materials in a small modular basal thumb joint implant, which heretofore did not exist. The one-piece thumb joint of Wright was made entirely of metal, thus teaching away from ceramic in the small joint and teaching away from not only modularity but also a combination of a ceramic head and a metal stem in such an implant. This is additional strong evidence of patentability. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; Roemer, 258 F.3d 1303 [59 USPQ2d at 1531].

5. Claim 37 is patentable over McLaughlin in view of the Wright Medical Technology brochure (Wright).

As explained above with respect to claim 21, McLaughlin does not render the base claim obvious since that patent has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant. Wright, if both McLaughlin and it could be applied, adds nothing that would render base claim 21 obvious. Accordingly, by virtue of its dependence on claim 21, claim 37 distinguishes over the proposed combination.

Moreover, Wright is not applicable by itself or with McLaughlin. The Wright implant is a one-piece basal thumb joint implant. The present claimed invention is a modular basal thumb joint implant. The Examiner has fully admitted at least two times of record that one-piece basal thumb joint implants and modular basal thumb joint implants are independent and patentably distinct species. See, the 05/25/01 Office action in the parent application, pages 2-3, from whence came the present divisional application; and, in the present application, the 10/12/2006 Office action, page 2, and the 01/17/2007 Office action, page 2. Thus, Wright is not related to the art of the present claims, and the Examiner has admitted it. McLaughlin, again which represents hip or shoulder implant art, as explained above with respect to claim 21, is not relevant art and not applicable. Nor is the basal thumb joint implant of Wright related to the shoulder or hip of McLaughlin. Only references related to the art of the claimed invention and related to other references in combination can be applied. See, Sernaker, 702 F.2d 989 [217 USPQ at 5]; Oetiker, 977 F.2d 1443 [24 USPQ2d at 1445-1446]. Moreover, even if these two disparate references could be applied to the present claims, they would not suggest the invention claimed. Among other things, Wright lacks a disclosure of modularity, a curved stem, a tri-flanged stem, an eccentric stem-to-head attachment site. Wright lacks disclosure of acute stem-to-head attachment; its attachment is perpendicular. Among other things, McLaughlin lacks disclosure of a head with a generally hemispherical articulating surface, size of the present claimed head and stem, generally acute site of attachment, tri-flanged stem, eccentric attachment, an inwardly curved stem, and so forth. If the features of these two references were combined, a person of ordinary skill would be left in the dark as to which features should be present: should there be a large head? a small stem? a square stem? if the size of the implant were made small, should not a tri-flange or curved stem be jettisoned in favor of a stout, square, straight stem, as found in Wright, which has the small implant? Clearly, too, if combined, there would be no modularity, or, if it were deemed that McLaughlin shows stem-and-head modularity as in a large hip joint implant, if a device were made small, modularity of stem-to-head should be jettisoned as taught by Wright; there would be a perpendicular stem-to-head attachment, not acuteness as claimed hereby; there would be stem-to-head attachment at the center of the rear of the

head, not in the eccentric manner claimed hereby. Thus, at best, the artificial combination has ambiguous teachings, which are not even general guidance, but even general guidance is not enough to establish a case of obviousness; moreover, much of the combined teachings, especially as found in both references and reinforced thereby, teach away from the present claims, which go against such wisdom, which is strong evidence of nonobviousness. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687]; Roemer, 258 F.3d 1303 [59 USPQ2d at 1531]. What is more, Dr. Leslie, a renowned hand surgeon, verified that he thought the one-piece basal thumb joint implant of Dr. Townley was a significant improvement over the implant of Wright; thus, if Wright were somehow considered relevant, its value is rebutted by that. See, Evidence Appendix, p. EA-8, first and third large paragraphs, p. EA-9, first paragraph.

6. Claim 42 is patentable over McLaughlin in view of ASTM F 1377-98.

Claim 42 depends on claim 40 and further requires a porous coating for bone interface.

As explained above with respect to claim 40, McLaughlin does not render the base claim obvious since that patent has no proper application, teaching or suggestion for the pertinent art of a modular basal thumb joint implant. The ASTM, if both McLaughlin and it could be applied, adds nothing that would render base claim 40 obvious. Accordingly, by virtue of its dependence on claim 40, claim 42 distinguishes over the proposed combination.

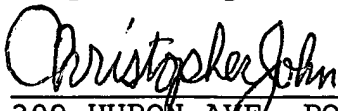
Moreover, combining these references would lead plainly to a device that could not operate in articulation with the concavely prepared surface of trapezium bone stock. Note that McLaughlin's proximal component 12 can be fixed with bony ingrowth. This is what is provided by the ASTM. However, that bony ingrowth would be found on the generally hemispherical surface of the proximal component 12, thus rendering it impossible to articulate. And so not only would the combination make for inoperable articulation but it teaches away from articulation with a generally hemispherical surface. This is strong evidence of patentability. See, Adams, 383 U.S. 39 [148 USPQ at 483]; Hedges, 783 F.2d 1038 [228 USPQ at 687].

Conclusion

Reversal of the rejections is in order, and is requested.

Respectfully submitted,

Dated: Feb. 6, 2008 A.D.



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Attmt